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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/460,715 06/02/95 MACH

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EXAMINER

WORTMAN, D

ART UNIT

PAPER NUMBER

1645

19

DATE MAILED:

04/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>08/460,715</b>	Applicant(s) <b>Mach et al.</b>
	Examiner <b>Donna C. Wortman, Ph.D.</b>	Group Art Unit <b>1645</b>

Responsive to communication(s) filed on 12/22/99 and 1/19/00

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 7, 8, and 19-39 is/are pending in the application

Of the above, claim(s) 7 and 8 is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 19-39 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 7, 8, and 19-39 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

Claims 19, 20, 21, 22, 23, and 24 were amended in Paper No. 17 filed December 22, 1999. Claim 19 was further amended and new claims 25-39 were added in Paper No. 18 filed January 19, 2000. Claims 7 and 8 remain pending and withdrawn from consideration as drawn to a non-elected invention. Claims 19-39 are pending and under examination.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 as last amended recites "A DNA construct ...". No support could be located in the specification for a product termed a DNA construct. This matter might be resolved if Applicant were to point to the location in the specification where this material is supported.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is indefinite in reciting "said DNA molecule does not comprise a HindIII R fragment" because it is not clear what the intended DNA does comprise and what the claim encompasses. Does the claim encompass a DNA molecule that consists of the relevant HindIII R fragment, minus one base pair, for example? The metes and bounds of the claim are entirely unclear.

Claims 25-37 are indefinite in reciting "contained within ...". Is it intended to claim the recited restriction fragments? Is it intended to claim all portions of the HCMV genome that are smaller than the HindIII R fragment, as long as the sequences that encode pp28 or antigenic portions of pp28 are present?

Claim 25 is indefinite in reciting "wherein said DNA molecule is contained within the HindIII fragment that includes pp28." First, it is not clear what is intended by a DNA molecule contained within a particular restriction fragment. It is not clear how a "DNA molecule" is different from a restriction fragment. Further, claim 25 is confusing because pp28 is a viral phosphoprotein and a HindIII fragment

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is a restriction fragment of the viral genome and it is not clear what is meant by a genome fragment that includes a protein.

Claims 26-36 are similarly confusing in reciting genome fragments that include a protein.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19 and 25-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Ihara et al. (Archives of Virology 88:241-250, 1986), of record. Ihara et al. disclose a HindIII R fragment which was recleaved with other restriction endonucleases, including XbaI, to generate a DNA fragment or molecule which is deemed to contain the relevant DNA (see Table 1, e.g.), as well as the cloning of HCMV HindIII restriction fragments. The HindIII/XbaI fragment anticipates the subject matter of claims 19 and 27-39, since the XbaI fragment is contained within the HindIII R fragment and contains all the other restriction fragments, except the HindIII/XhoI fragment of claim 26. The HindIII R fragment anticipates the subject matter of claims 25-37 and 39 since it comprises all the recited fragments; cloning of the HindIII R fragment anticipates claim 38.

Applicant has previously argued that Ibara does not disclose which portion of the fragments encodes pp28.

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This argument is not found persuasive because the claims are not clearly limited to DNA that encodes pp28; the fragments disclosed by Ibara inherently contain the recited material.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ibara et al., cited above. The teachings of Ibara with respect to cloning of HCMV restriction fragments are cited above. While Ibara does not exemplify cloning of each DNA taught, it would have been obvious to clone an HCMV DNA of interest because Ibara teaches the interest in and value of cloning HCMV DNA, i.e., for the purpose of constructing cleavage maps of the HCMV genome.

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This application contains claims 7 and 8 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 1.17(e) were filed prior to or with the payment of the fee set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened

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statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Wortman whose telephone number is (703) 308-1032. The examiner can normally be reached on Monday through Thursday from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Donna Wortman, Art Unit 1645, and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1645 FAX telephone number for official papers is (703) 308-4242. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday, or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.



Donna C. Wortman, Ph.D.  
Primary Examiner

April 7, 2000